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B. 510(k) SUMMARY (as required by 21 CFR 807.92)

Excia Total Hip System Line Extension
June 13, 2006

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Lisa M. Boyle
610-984-9274 (phone)
610-791-6882 (fax)

TRADE NAME: Excia

COMMON NAME: Excia Total Hip System

DEVICE CLASS: Class II

REGULATION NUMBER: 888.3353, 888.3350, 888.3360

PRODUCT CODE: LZO, JDI, and LWJ

REVIEW PANEL: Orthopedic

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Acetabular Cups (Plasmacup® NSC and MSC) are substantially equivalent to the Acetabular Cups (Plasmacup® SC) that are cleared in the Excia Total Hip System (K042334).

DEVICE DESCRIPTION

The Acetabular Cups (Plasmacup® NSC and MSC) are manufactured from Ti. and are offered with a plasmapore® coating. The Plasmacup® is offered in two designs: NSC and MSC (no holes or multiple holes). Both designs are available in sizes ranging from 40mm – 68mm. The new Plasmacup® Acetabular Cups are a line extension to the existing Excia Total Hip System.

INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral ephiphysis

- Patients suffering from disability due to previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCr and intended for cemented fixation. The other femoral stem is for uncemented fixation and is manufactured from Ti. With a Ti. Plasma spray.

TECHNOLIGICAL CHARACTERISTICS (compared to Predicate(s))

The new Plasmacup® NSC and MSC acetabular cups of the Excia Total Hip System are offered in similar shapes and sizes as the predicate devices. The material used for the Aescualp device is the same as that used to manufacture the predicate device.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems and
- "Data Requirements for Ultrahigh Molecular Weight Poletheylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 1 8 2006

Aesculap, Inc.
% Ms. Lisa M. Boyle
Regulatory Specialist
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K061699
Trade/Device Name: Excia Total Hip System Line Extension
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, LWJ
Dated: July 25, 2006
Received: July 26, 2006

Dear Ms. Boyle:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

A. INDICATIONS FOR USE STATEMENT

510(k) Number: K061699

Device Name: ***Excia Total Hip System Line Extension***

Indications for Use:

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
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Prescription Use X and/or Over-the-Counter Use _____

(per 21 CFR 801 Subpart D) (per 21 CFR 801 Subpart C)

Barbara Bucher

(Division Sign-Off) (PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of General, Restorative, and Neurological Devices

510(k) Number K061699